REMARKS

The Official Action dated November 29, 2007 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 30 is amended to further define the invention in accordance with the teachings of the present specification, for example, at page 4. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Claims 30, 31, 33, 34 and 36 were rejected under 35 U.S.C. §102(b) as being anticipated by Duro et al, *FEBS Letters*, 399 (1996), 295-298. The Examiner asserted that Duro et al teach contacting serum from an individual known to be weed pollen allergic (i.e., *P. judaica* pollen allergic) with recombinant Par j 2 to detect pollen allergy and that the characterization of the recombinant antigen is a preliminary step for use of the protein therapeutically. The Examiner concluded that the prior art teaches all of the method steps of the claimed invention and therefore anticipates the claimed invention as the preamble adds no additional limitations to the claims since the same product was used in the same method steps for identifying allergens from patients.

In response to Applicants' previous arguments, the Examiner asserted that Duro et al need not provide a teaching or suggestion that Par j 2 is a pure allergen component with limited or no cross-reactivity as the present specification shows the inherency of the claimed method. According to the Examiner, whether or not individuals in the prior art were knowingly being serologically identified as *Parietaria* allergic is not necessary as the method is inherently identifying them. The Examiner cited *Atlas Powder Company v. IRECO*, 51 USPQ 2d 1943 (Fed. Cir. 1999), as supporting the Examiner's assertion that it is not

necessary that those of ordinary skill in the art at the time of the invention knew that Par j 2 had limited or no cross-reactivity.

However, Applicants submit that the methods defined by claims 30, 31, 33, 34 and 36 are not anticipated by and are patentably distinguishable from the teachings of Duro et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 30, the invention is directed to a method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic, which method comprises selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, and selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity. The method further comprises contacting serum from the selected individual known to be weed pollen allergic with the selected pure allergen component, which is pure Par j 1 or Par j 2 allergen component, determining the presence of IgE binding to said pure Par j 1 or Par j 2 allergen component; and identifying the individual as *Parietaria* allergic if the contacted serum contains IgE binding to said pure allergen component.

Thus, the present methods are for accurately identifying a *Parietaria* allergic individual, particularly when the individual is known to be generally weed pollen allergic but it is not known if the individual is *Parietaria* allergic. Applicants have determined that *Parietaria* pollen extract binds IgE from individuals not exposed to *Parietaria* pollen, while the recited pure allergen component Par j 1 or Par j 2 does not bind to IgE from such individuals. However, Par j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen, as does Par j 1. Thus, Applicants have developed the present methods for specific identification of *Parietaria* allergic individuals from those known to be weed pollen allergic using a pure allergen component known to have limited or no cross-reactivity.

Duro et al fail to teach a method for serologically identifying an individual known to be weed pollen allergic wherein it is not known if the individual is *Parietaria* allergic, as *Parietaria* allergic. That is, the Duro et al publication is directed to a single allergen source, namely *Parietaria judaica* pollen, and does not mention other allergen sources or individuals known generally to be weed pollen allergic. While Duro et al seek to characterize one of at least 9 allergen components of this source, namely Par j 2, Duro et al are not concerned with any other allergy source. Further, by showing that 82% of the *Parietaria judaica* pollen sensitive patients' serum had IgE reacting with Par j 2, Duro et al merely show that Par j 2 is a major allergen (see page 297, right column, lines 18-21), and no other findings or conclusions are provided by Duro et al. Particularly, Duro et al do not teach or suggest that Par j 2, or any other pure allergen component, can be employed in order to serologically identify with improved accuracy a *Parietaria* allergic individual from a general weed pollen allergic individual, as recited in the present claims. In fact, while claim 30 recites the step of selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, Duro et al employs serum from individuals known to be *Parietaria* allergic. Further, while claim 30 requires selecting a pure *Parietaria* allergic component known to have limited or no cross-reactivity, Duro et al fail to teach, suggest or recognize that Par j 2 has limited or no cross-reactivity.

The Examiner attempted to disregard these deficiencies in the teachings of Duro et al. First, the Examiner asserted that whether or not individuals in the prior art were knowingly being serologically identified as *Parietaria* allergic is not necessary as the method is inherently identifying them. However, the claimed invention is specifically directed to a method for identifying such individuals. If the prior art does not recognize the individuals as identified as *Parietaria* allergic, the prior art does not teach the claimed method. The Examiner also relied on *Atlas Powder Company v. IRECO*, supra, as supporting the

Examiner's theory of inherency. However, the *Atlas Powder* case relates to inherent characteristics or functioning of a prior art composition or ingredient and does not provide any guidance regarding the inherency of a claimed method. Particularly, *Atlas Powder* provides no support for the Examiner's conclusion that Duro et al inherently identify *Parietaria* individuals, particularly in view of Duro et al's previous knowledge of the individuals as *Parietaria* allergic and Duro et al's failure to teach, suggest or recognize any method for such identification.

The Examiner cited to Aalberse et al and Weber et al as supporting the position that cross-reactivity cannot be assumed to be present between any two allergens that are not 100% identical. Not only do these references not support the Examiner's assertion, the Examiner's assertion is not relevant to the present issue of patentability and the evidence of record. It is well established and demonstrated by the data set forth in the present specification that there is significant cross-reactivity between weed pollens, such as ragweed, mugwort, and *Parietaria* pollen extracts. Such extracts contain a plurality of allergen components, at least some of which are cross reactive. Thus, the Examiner's assertions regarding Aalberse et al and Weber et al are irrelevant to the determination of the patentability of the present claims which involve selection of an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, and selecting a pure allergy component known to have limited or known cross reactivity. That is, the method of claim 30 recites, *inter alia*, the step of selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity which is pure Par j 1 or Par j 2 allergen component.

Importantly, Duro et al provide no teaching or suggestion that Par j 2 is a known pure allergen component with limited or no cross-reactivity. The previously submitted Declaration Under 37 C.F.R. 1.132 of the co-inventor Dr. Paolo Colombo confirms that the Duro et al paper does not disclose or suggest that the Par j 2 allergen has limited or no cross-

reactivity with allergen components from other weed pollen allergen sources (paragraph 4) and thus does not teach or suggest using Par j 2, or any other purified allergen component, in methods for diagnosis of the actual sensitizing source from a variety of possible allergen sources (paragraph 4). Further, while the Examiner asserted that Applicants' own specification and claims show that Par j 2 is inherently diagnostic of *Parietaria judaica* pollen allergy, the teachings of Applicants' specification and claims are not available as prior art to interpret what the Duro et al teachings would mean to one of ordinary skill in the art. As Duro et al do not teach or suggest that Par j 2 is a pure allergen component with limited or no cross-reactivity, and therefore suitable for use in identifying an individual known to be weed pollen allergic as *Parietaria* allergic, Duro et al do not disclose a method for such identification.

Only in light of Applicants' specification can the Examiner conclude that the 18% of patients having serum which do not react with Par j 2 are inherently not allergic to *Parietaria judaica* and therefore must be allergic to another allergen from another allergen source while the 82% of patients having serum that reacts with Par j 2 are *Parietaria* allergic. Contrary to the Examiner's assertion that Duro et al need not "teach" that Par j 2 is non-cross-reactive, the step of selecting a pure *Parietaria* allergen component known to have limited or no cross-reactivity of claim 30 requires that Duro et al must provide this very teaching in order to anticipate the claimed method for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

Applicants have established, contrary to the Examiner's unsupported assertions, that weed pollens are well known to be cross-reactive. It should be noted however, that the Examiner's burden is to establish that the claimed steps, including the steps of selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, and selecting a pure *Parietaria* allergen component known to have

limited or no cross-reactivity, are disclosed in the prior art. It is not Applicant's burden under 35 U.S.C. §102(b) to show that the prior art does not disclose these steps unless and until the Examiner has made a prima facie showing of anticipation. The Examiner has not made any such prima facie case of anticipation herein. To the contrary, Applicants specification presents substantial evidence of the knowledge in the art that weed pollens are well known to be cross-reactive. Thus, the failure of Duro et al to teach that Par j 2 is non-cross-reactive demonstrates that Duro et al do not teach the presently claimed methods for serologically identifying with improved accuracy an individual known to be weed pollen allergic as *Parietaria* allergic.

Duro et al disclose the cloning and characterization of the allergen Par j 2.0101, and generally mention that in a diagnostic/therapeutic approach, a preliminary step is to purify and characterize each major allergen. This is only a general statement relating to all allergens and all diagnostic and therapeutic strategies. Applicants find no teaching or suggestion regarding any specific diagnostic method or approach. Particularly, Applicants find no teaching or suggestion by Duro et al regarding a method for accurately identifying a *Parietaria* allergic individual.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Duro et al to teach a method for serologically identifying an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic, as *Parietaria* allergic, particularly by selecting and employing pure Par j 1 or Par j 2 allergen component known as having limited or no cross-reactivity, Duro et al do not anticipate the methods of claims 30-36. Accordingly, the rejection under 35 U.S.C. §102 has been overcome. Reconsideration is respectfully requested.

Claims 30-32, 34 and 35 were rejected under 35 U.S.C. §102(b) as being anticipated by Costa et al, *FEBS Letters*, 341 (1994), 182-186. The Examiner asserted that Costa el al teach serologically identifying an individual known to be weed pollen allergic by contacting serum from an individual known to be *Parietaria judaica* pollen allergic with recombinant Par j 1 and the use of Par j 1 T and B cell epitopes in immunotherapy.

However, Applicants submit that the methods defined by claims 30-32, 34 and 35 are not anticipated by and are patentably distinguishable from the teachings of Costa et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The method defined by independent claim 30 is discussed in detail above. Costa et al disclose the cDNA cloning, expression and primary structure of Par j 1 as a major allergen of *Parietaria judaica* pollen. Costa et al note that the allergenic composition of the *Parietaria* pollen is composed of a complex mixture of at least 26 antigens, 9 of which have been shown to bind specifically to IgE of allergic patients, and Par j 1 is discussed in detail by Costa et al. However, Costa et al, like Duro et al, employ serum from patients allergic to *Parietaria judaica* (Section 2.2, Page 183). Thus, Costa et al, like Duro et al, fail to disclose a method for serologically identifying an individual known to be weed pollen allergic as *Parietaria* allergic by, inter alia, selecting an individual known to be weed pollen allergic, wherein it is not known if the individual is *Parietaria* allergic. Further, Costa et al, like Duro et al, fail to teach, suggest or recognize that pure Par j 1 is known to have limited or no cross-reactivity. Thus, Costa et al, like Duro et al, fail to teach, suggest or recognize that pure Par j 1 is suitable for use in serologically identifying with improved accuracy such a selected individual as *Parietaria* allergic. Accordingly, all of the deficiencies of Duro et al discussed in detail above apply equally well with respect to Costa et al.

Thus, in view of the failure of Costa et al to teach a method for serologically identifying an individual known to be weed pollen allergic, wherein it is not known if the

individual is *Parietaria* allergic, as *Parietaria* allergic, particularly by selecting and employing pure Par j 1 or Par j 2 allergen component, known as having limited or no cross-reactivity, Costa et al do not expressly or inherently describe each and every element as set forth in the present claims and therefore do not anticipate claim 30, or claims 31, 32, 34 or 35 dependent thereon, under 35 U.S.C. §102. *In re Robertson*, supra. Accordingly, the rejection based on Costa et al has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Official Action.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 50-3915

Respectfully submitted,

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